# Complete Phase 1b Dataset: EDP1815 in Atopic Dermatitis



January 20, 2021

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## Phase 1b clinical trial design

#### **Trial Summary**

- Double-blind, placebo-controlled trial of 24 patients
- Mild and moderate atopic dermatitis\*, randomized 2:1 (active: placebo)
- 56 days of oral administration of enteric capsule formulation, follow-up at day 70
- Once daily
- No active topical treatments, no requirement to use emollients

#### \*Baseline Disease Severity

*Inclusion criteria:* 

- IGA 2 or 3
- BSA 5-40%

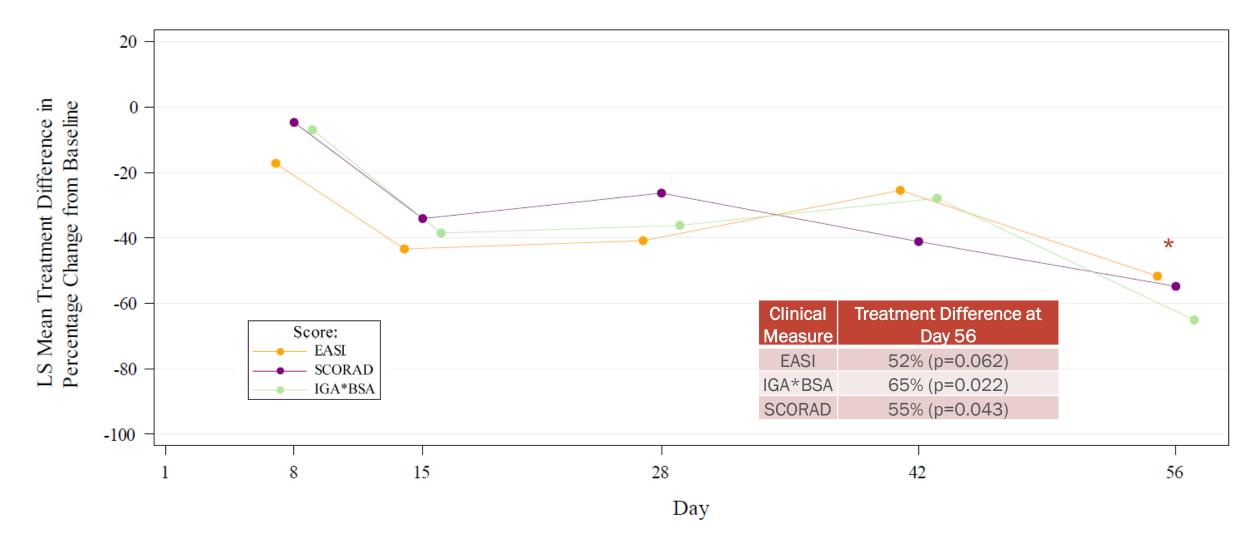
Mean baseline characteristics	EDP1815 (n=16)	Placebo (n=8)
EASI	8.31	9.31
IGA	2.63	2.75



## No topical therapies required for patients for >8 weeks

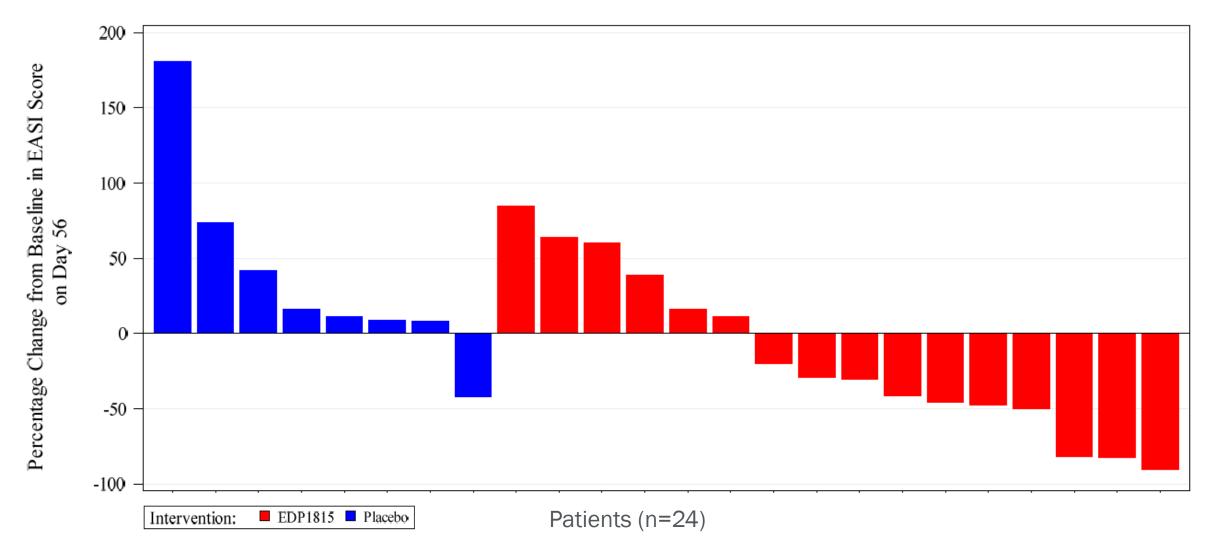
- No topical steroids permitted at any point
- Topical emollients permitted to be used <u>only</u> if the patient was already using regularly prior to entry into trial
- Low rate of topical emollient use:
  - Placebo: 2 of 8 (25%) applied emollient regularly
  - EDP1815: 4 of 16 (25%) applied emollient regularly
- Phase 2 and 3 trials would include at least daily emollient use

## Improvements in EASI, IGA\*BSA, and SCORAD at day 56





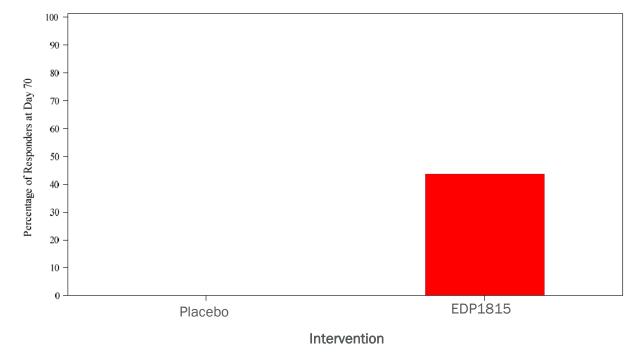
# EASI: 10/16 patients on EDP1815 improved at day 56



# 44% of EDP1815 patients achieved EASI50

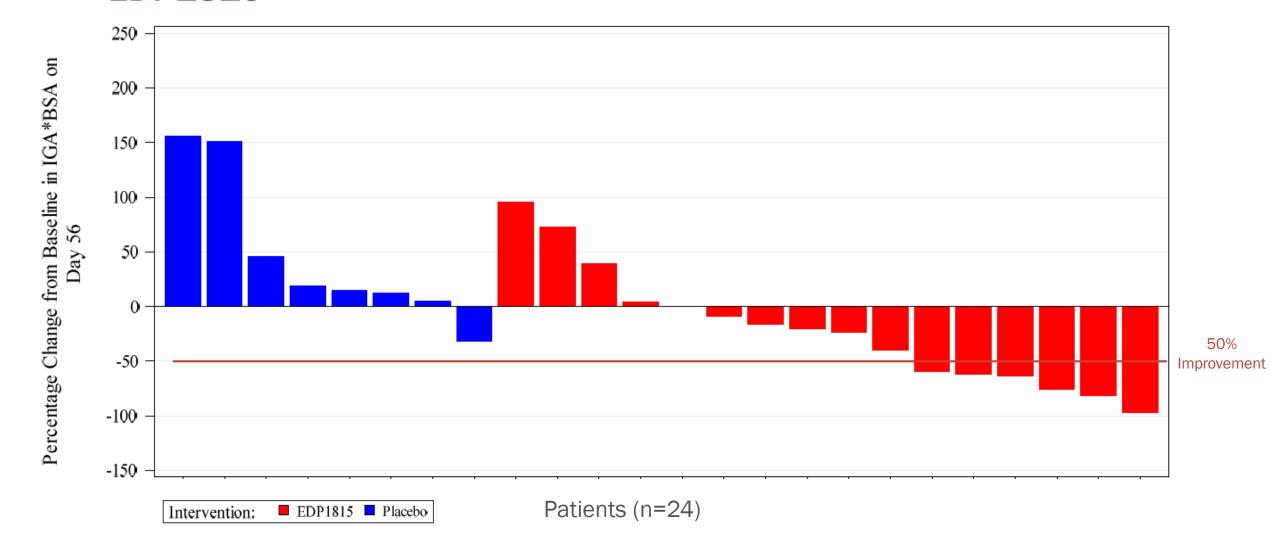
Clinical Measure	Placebo	EDP1815
EASI50 day 56	0/8 (0%)	4/16 (25%)
EASI50 day 70	0/8 (0%)	7/16 (44%)

#### EASI50 response at day 70





# IGA\*BSA: 6 patients achieved a >50% improvement at day 56 with EDP1815



# Clinically meaningful improvements in Patient-Reported Outcomes at day 56, including itch and sleep

Patient-Reported Outcome	EDP1815 Mean change, day 56 (mean % change per patient)	<b>Placebo</b> Mean change, day 56 (mean % change per patient)
DLQI (Dermatology Life Quality Index)	-3.6* (-35%)	-0.3 (+46%)
POEM (Patient-Oriented Eczema Measure)	-4.1 <b>*</b> (-21%)	+1.6 (+22%)

<sup>\*</sup>Mean improvement exceeded the minimally clinically important difference<sup>1,2</sup>

- EDP1815 led to improvement in itch across all measured scores at day 56
- EDP1815 led to improvement in sleep across all measured scores at day 56

<sup>2.</sup> Schram ME, Spuls PI, Leeflang MM, Lindeboom R, Bos JD, Schmitt J. EASI, (objective) SCORAD and POEM for atopic eczema: responsiveness and minimal clinically important difference. Allergy. 2012 Jan;67(1):99-106. doi: 10.1111/j.1398-9995.2011.02719.x. Epub 2011 Sep 27. PMID: 21951293.



Basra MK, Salek MS, Camilleri L, Sturkey R, Finlay AY. Determining the minimal clinically important difference and responsiveness of the Dermatology Life Quality Index (DLQI): further data. Dermatology. 2015;230(1):27-33. doi: 10.1159/000365390. Epub 2015 Jan 20. PMID: 25613671.

# Efficacy of oral EDP1815 in atopic dermatitis



Patient on once daily oral EDP1815 and no topical treatments: before and after (patient achieved EASI50 score)





#### **Conclusions**

- 1. Consistent results observed across all atopic dermatitis measures
- 2. Progressing into Phase 2 clinical trial in atopic dermatitis
- 3. EDP1815 has now shown clinical activity in both psoriasis and atopic dermatitis patients

# Patient need in mild and moderate atopic dermatitis

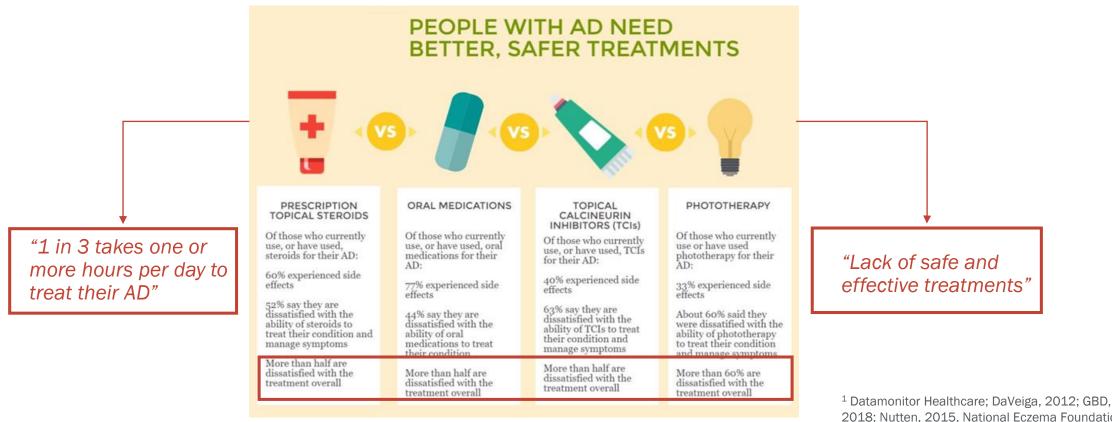






# Hundreds of millions of patients worldwide live with atopic dermatitis, most with no meaningful treatments

15-20% of children and 3-6% of adults worldwide<sup>1</sup> are estimated to suffer from atopic dermatitis





# SINTAX medicines potentially applicable across spectrum of inflammatory diseases- plan to capture full breadth in staged manner

Proof of concept results from First wave of potential Examples of potential second wave expansion programs currently studied indications expansion programs Lichen planus Acne **PSORIASIS**  Alopecia areata Sarcoidosis Reduction in skin lesions vs Psoriatic arthritis • Chronic obstructive pulmonary disease • Sjögren's syndrome placebo in 2 cohorts Axial spondylarthritis\* Crohn's disease Ulcerative colitis Th17 focused Systemic Inhibition of multiple Rheumatoid arthritis\* Giant cell arthritis Vitiligo inflammatory cytokines Hidradenitis suppurative • Scleroderma / Systemic sclerosis Ongoing Phase 2b trial Inflammatory myopathies Eosinophilic granulomatosis Allergic bronchopulmonary ATOPIC DERMATITIS aspergillosis with polyangiitis Improvement in atopic Allergic rhinitis Hypereosinophilic syndrome Asthma Th2 focused dermatitis vs placebo Allergy Bullous pemphigoid Prurigo nodularis Positive results provide basis Chronic spontaneous urticaria Nasal polyps for Phase 2b · Eosinophilic esophagitis Crohn's disease Axial spondylarthritis Sjögren's syndrome **HUMAN KLH** · Giant cell arthritis Rheumatoid arthritis Systemic lupus erythematosus Th1 focused Hidradenitis suppurativa >90% reduction in Psoriasis\* Lupus nephritis Inflammatory myopathies inflammation vs placebo Psoriatic Arthritis\*

<sup>\*</sup>Simplified and non-exhaustive view of inflammation. Many inflammatory diseases are complex and involve multiple arms of the immune system



# Pipeline is rich in anticipated near-term clinical catalysts

Candidate	Catalyst	
EDP1815 Psoriasis	1Q 2021: Phase 1b tablet formulation trial initiation 3Q 2021: Phase 1b tablet formulation data 2Q 2021: Phase 2 interim data 2H 2021: Full Phase 2 dataset 1H 2022: Phase 3 initiation*	
EDP1815 Atopic dermatitis	3Q 2021: Phase 2 initiation 1Q 2022: Phase 2 interim data 2022: Phase 3 initiation*	
EDP1815-TACTIC-E COVID-19	2Q 2021: Phase 2/3 interim safety data and futility analysis	
EDP1815-Rutgers University COVID-19	<b>2Q 2021:</b> Phase 2 data	
EDP1867 Atopic dermatitis	1Q 2021: Phase 1b initiation 4Q 2021: Phase 1b data	
EDP2939 Inflammation	2022: Phase 1b initiation	
EDP1908 Oncology	2022: Phase 1 initiation	
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